Appl. No. 09/750,086 Amdt. Dated: January 5, 2004
Reply to Office action of July 9, 2003

Amendments to the Specification:

Please replace the paragraphs beginning at page 3, line 15, with the following amended paragraphs:

In the embodiment described, the body 10 defines in part a first vessel 42 having a first socket 12 communicating with and extending from an end thereof which receives an end of the syringe 2 equipped with a luer 14 (see Figure 23) provided with a closure in the form of a rubber cap 16. On activation of the syringe, the cap 16 is forced into a narrowed portion 18 of the socket such that a needle or cannula 20 penetrates the cap (see Figure 4). Other broaching means could be used; for example, the closure could be provided by a plug axially displaceable within a neck of the syringe so as to open a passageway, the plug being displaced by broaching means in the form of a rod replacing the needle.

The first vessel 42 is only one of three vessels contained within or defined by the body 10. A second vessel 44 communicates at one end with a second socket 22 extending from the vessel 44. The second socket is configured to receive at least part of the second container, typically a pharmaceutical vial 24, including a neck 26 and closure 28 of the vial. On actuation, the neck 26 of the vial is forced into a narrowed portion of the socket 2224 so that the closure 28 is broached by a cannula 32. As in the case of the first container, alternative closures and broaching means are possible. The vial contains a second component of the pharmaceutical. Typically, the syringe will contain a first component in the form of a liquid solvent, diluent or suspension medium for a liquid or solid second component in the vial but other arrangements are possible, provided that at least one component is liquid.

In the embodiment shown, the sockets 12 and 22 have tubular extensions, 13 and 23 respectively, the tubular extensions being welded together so as to enclose the first and second vessels 42 and 44 which extend from a valve assembly 40, and support a third vessel 5246 of the assembly which projects through a side wall 48 of a chamber 50 formed by cooperation of the extensions 13 and 23. Open ends of the vessels 42 and 44 communicate with the sockets 12 and 22 through the cannulas 20 and 32. The third vessel 5246 projects through the side, and its open end 4652 receives a flexible tubulation 54 through which a reconstituted pharmaceutical may

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be dispensed from the system, for example, to a connector 59 which may be coupled to a nozzle (not shown) to provide a catheter for introduction into a body orifice. It will be noted that the tubular extensions are welded together so that the sockets 12 and 22 are coaxial, thus providing a strong structure, and facilitating proper relative orientation of the syringe 2 and vial 24 during reconstitution of the pharmaceutical.

Also projecting through the wall 48 is an actuator lever 56 which moves a valve member 58 between a first position and a second position. The first position forms a passage, defined by the valve member, establishing communication between the first vessel 42, and the second vessel 44. The second position forms a passage defined by the valve member establishing communication between the first vessel and the open end 4652 of the third vessel 5246.

Please replace the paragraphs beginning at page 5, line 2, with the following amended paragraphs:

In use, starting with the system shown in Figure 1, it is checked that the lever 56 is set so that the valve member is in the first position permitting fluid communication between the first and second vessels (42 and 44). The caps 60 and 62 are flipped off as shown in Figure 3. As shown in Figure 4, the vial 24 is then pressed into the second socket 2221 as shown in Figure 4 such that the neck 26 of the vial is forced into the portion of the socket so that the closure 28 is penetrated by the cannula 32. The syringe is pressed in the direction of arrow 62, into the socket 12. The cap 16 is forced into a narrowed portion of the socket causing the cannula 20 to penetrate the cap 16.

At this point, the first vessel <u>42</u> and the syringe 2 are in fluid communication with the second vessel <u>4422</u> and the vial 24. Then, the plunger 8 is actuated so as to eject fluid through the valve member 58 into the vial 24 (see Figure 5). If the syringe contents A are a liquid, the transferred liquid is swilled in the vial to dissolve, suspend or dilute the content B of the vial, and the resulting liquid is aspirated back into the syringe by manipulation of the plunger 8 (Figure 6) in the direction of arrow 66. If only the content of the vial is liquid, then the plunger may be used to force gas from the syringe into the vial which is used to aspirate liquid from the vial back into the syringe to dissolve or suspend the content of the latter. In either case, after

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aspiration, the assembly may then be inverted several times to complete dissolution, admixture or suspension. It should be noted that no additional vents or the like are required in or between the syringe 2 and the vial 24, the sole communication being through the vessels 42 and 44.

The lever 56, as shown in Figure 7, is moved to reposition the valve member to a position in which it connects the <u>third vessel 52 and the first vessel 42first 12</u> and second 22 vessels, which enables the syringe to be utilized to deliver the content of the latter into the catheter formed by tubulation 54. The syringe plunger may be actuated manually, or with the assistance of a syringe actuator connected to or in place of the plunger 8.

Please replace the paragraph beginning at page 6, line 12, with the following amended paragraph:

The empty syringe 2 with its plunger 8 located so that the piston 4 is adjacent the luer 14, is fully inserted in the socket 12 so that a penetrable diaphragm of the cap 16 is broached (see Figure 9), and the vial <u>244</u> is likewise fully inserted into the socket 22. The valve member 58 is moved to its second position, establishing communication between the syringe 2 and the tubulation 54. The needle 72 is applied to the adaptor 59, and inserted into a nozzle 74 of the bag. The plunger 8 is then withdrawn with the piston 4 so as to aspirate liquid, such as sterile water or saline solution, from the bag 70 into the syringe 2. The valve member 58 is then moved to its first position, and the needle and bag are removed from the adaptor 59, from which point reconstitution proceeds as already described with reference to Figures 5 to 7.